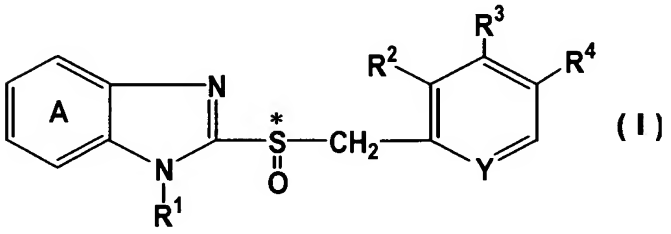
CLAIMS

1. A stable solid dosage form comprising a non-toxic base and an amorphous benzimidazole compound having a proton pump inhibitor (PPI) activity.

2. The solid dosage form according to claim 1, wherein the benzimidazole compound is an optically active isomer.

3. The solid dosage form according to claim 2, wherein the optically active isomer of benzimidazole compound is a compound represented by the formula (I):



(I)

wherein ring A is an optionally substituted benzene ring, R^1 is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group, R^2, R^3 and R^4 are the same or different and each represent a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, Y represents a nitrogen atom or CH, and * represents asymmetric center, or a salt thereof.

4. The solid dosage form according to claim 2, wherein the optically active isomer of benzimidazole compound is an optically active isomer of lansoprazole, omeprazole, rabeprazole or pantoprazole.

5. The solid dosage form according to claim 2, wherein the optically active isomer of benzimidazole compound is an optically active isomer of lansoprazole.

6. The solid dosage form according to claim 5, wherein the optically active isomer of lansoprazole is R-isomer.

7. The solid dosage form according to claim 5, wherein the optically active isomer of lansoprazole is S-isomer.

8. The solid dosage form according to claim 1, wherein the non-toxic base is an inorganic salt of which 1% aqueous solution or 1% aqueous suspension shows a pH value of 8.0 or more at 25°C.

9. The solid dosage form according to claim 1, wherein the non-toxic base is one or more basic inorganic salt selected from the group consisting of magnesium carbonate, calcium carbonate, magnesium hydroxide, magnesium oxide, sodium carbonate, sodium bicarbonate and sodium hydroxide.

10. The solid dosage form according to claim 1, which has a coating layer.

11. The solid dosage form according to claim 10, wherein the coating layer contains an enteric coating layer.

12. The solid dosage form according to claim 10, wherein the coating layer contains a controlled release coating later.

13. The solid dosage form according to claim 10, wherein the coating layer contains an intermediate coating layer

formed on a layer containing an amorphous benzimidazole compound and a controlled release coating later and/or enteric coating layer formed on said intermediate coating layer.

14. The solid dosage form according to claim 1, wherein the non-toxic base contains at least one component selected from metal oxides and at least one component selected from metal hydroxides.

15. The solid dosage form according to claim 14, which is gastric disintegrable.

16. The solid dosage form according to 14, which comprises at least one metal oxide selected from the group consisting of magnesium oxide, magnesium silicate, dry aluminum hydroxide gel and magnesium metasilicate aluminate.

17. The solid dosage form according to claim 14, which comprises at least one metal hydroxide selected from the group consisting of magnesium hydroxide, aluminum hydroxide, synthetic Hydrotalcite, coprecipitate of aluminum hydroxide and magnesium hydroxide, coprecipitate of aluminum hydroxide, magnesium carbonate and calcium carbonate, and coprecipitate of aluminum hydroxide and sodium bicarbonate.

18. The solid dosage form according to claim 14, which comprises further a basic inorganic salt stabilizer with a carbonate of alkaline earth metal.

19. A stabilized solid dosage form which comprises a layer

containing an amorphous optically active R-isomer of lansoprazole and at least one basic inorganic salt selected from the group consisting of magnesium carbonate, calcium carbonate, magnesium hydroxide, magnesium oxide, sodium carbonate, sodium bicarbonate and sodium hydroxide, an intermediate coating layer formed on said layer, and an enteric coating layer formed on said intermediate coating layer.

20. The solid dosage form according to claim 19, wherein the basic inorganic salt is magnesium carbonate or calcium carbonate.

21. A process for manufacturing a stable solid dosage form containing an amorphous benzimidazole compound having a PPI activity, which is packed in the packaging configuration selected from the group consisting of oxygen permeation inhibitory packaging, gas exchanged packaging, vacuum packaging and deoxidant-encapsulated packaging.

22. The manufacturing process according to claim 21, wherein a non-toxic base is compounded.

23. A process for producing an amorphous optically active isomer of lansoprazole which comprises keeping hydrated crystals of optically active isomer (R-isomer) of lansoprazole at about 20 to about 100°C.

24. The process for producing an amorphous optically active isomer of lansoprazole according to claim 23, which

comprises heating at about 40 to about 80°C.

25. The process according to claim 23, wherein 0.5 to 1.5 hydrate crystals of optically active isomer (R-isomer) of lansoprazole is heated at about 50 to about 70°C.

26. The process according to claim 23, wherein the keeping of the temperature is carried out under reduced pressure or under ventilation.